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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,685	10/15/2003	Anthony Costa	0299568-0417	7079

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IP Department
Schnader Harrison Segal & Lewis LLP
Suite 3600
1600 Market Street
Philadelphia, PA 19103

EXAMINER

SILVERMAN, ERIC E

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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05/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/685,685

Applicant(s)

COSTA ET AL.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10 and 12-24 is/are pending in the application.
- 4a) Of the above claim(s) 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-10 and 12-17 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/16/2007 has been entered.

Pursuant to amendment, claims 1, 5 – 10 and 12 – 24 are pending, and claims 18 – 24 are withdrawn as non-elected. Claims 1, 5 – 10, and 12 – 17 are discussed on the merits in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5 – 10 and 12 – 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (A)). These include: nature of the invention, breadth of the claims, guidance of the

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specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims recite a gel matrix composition comprising about 15% w/w of a polyethylene glycol-150/decyl alcohol/saturated dicyclohexyl-methane diisocyanate copolymer (known in the art by the trademarked name Aculyn-44). The composition has a viscosity of 35 – 55 centipoises.

State of the prior art: Aculyn-44 is recognized in the art as a thickening agent. According to the "Aculyn 44" disclosure by Rohm and Haas (see PTO 892), adding even small amounts of Aculyn 44 increases the viscosity of a solution. On page 7 of that disclosure, a graph shows the effect of solution pH on solution viscosity for varying concentrations of Aculyn 44 (note that the viscosity on the graph's y-axis is measured in mPa-s, which is another term for centipoises). At 1% by weight Aculyn-44, the solution viscosity is about 100 centipoises. The solution pH has no effect at any physiologically acceptable pH (the viscosity begins to change appreciably at pH of about 12, but such a solution with such pH is caustic to the skin and other parts of the human body, and therefore not useful in the context of this invention). At 2% Aculyn 44, the solution viscosity is approximately 1,000 centipoises (again, this value is irrespective of pH across useful pH values). It is important to note that the percentages in the disclosure are in terms of percent of polymer solids, and thus, are comparable to the claim language, which requires 15% of the polymer itself. This is important, because the art

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sometimes uses the term "Aculyn 44" to refer to a concentrated solution of the named polymer, not the polymer itself. However, since the reference relied on here specifies that the percentages are based on polymer solids, comparison with the claim language and the results in the specification is valid.

Existence of working examples/specification: The specification discloses an example with about 15% Aculyn, but does not teach the viscosity of the resulting composition. The specification states that "an initial viscosity of about 50 centipoises (35-55 centipoises) is sought, however, there is nothing to indicate that this viscosity has been achieved, or if so, how this viscosity has been achieved. Applicant also does not take into account in the specification or through working examples that the artisan would expect a solution with 15% of the recited polymer to have a much higher viscosity. Applicant has not taught how to reach the viscosity required by instant claims in a composition containing 15% 15% w/w of a polyethylene glycol-150/decyl alcohol/saturated dicyclohexyl-methane diisocyanate copolymer.

Amount of experimentation necessary: In order to make the claimed gel matrix, one would have to determine a way to circumvent the art-disclosed viscosifying effects of the polyethylene glycol-150/decyl alcohol/saturated dicyclohexyl-methane diisocyanate copolymer in the claims. The artisan would have to figure out how to make a composition with 15% of this polymer and still arrive at a viscosity that is about half of the viscosity that would be expected if only 1% of the polymer were used. There is nothing in the art that would teach the artisan how to effect this change, and the specification provides insufficient guidance. Indeed, the evidence of record shows that

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simple changes to the solution, such as pH changes, will not serve to alter the viscosity of polyethylene glycol-150/decyl alcohol/saturated dicyclohexyl-methane diisocyanate copolymer solutions.

The experimentation needed to make the instantly claimed compositions is undue, and as such, the claims are not enabled.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1 and 15 under 35 U.S.C. 103(a) as being unpatentable over US 6,074,438 to Lim et al. is **withdrawn**.

The rejection of claims 5 – 10, and 12 under 35 U.S.C. 103(a) as being unpatentable over US 6,074,438 to Lim in view of US 6,447,788 to Strathausen is **withdrawn**.

The rejection of claims 15 and 16 under 35 U.S.C. 103(a) as being unpatentable over Lim in view of Strathausen and Lambrechts is **withdrawn**.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric E. Silverman, PhD
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